

AVI BIOPHARMA INC
Form 8-K
March 14, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 11, 2011

AVI BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Oregon
(State or other jurisdiction
of incorporation)

001-14895
(Commission
File Number)

93-0797222
(IRS Employer
Identification No.)

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3450 Monte Villa Parkway, Suite 101

Bothell, WA 98021

(Address of principal executive offices, including zip code)

(425) 354-5038

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On March 11, 2011, we received a letter (the Letter) from the U.S. Food and Drug Administration (FDA) indicating that our initial response to a clinical hold letter from the FDA for AVI-7100, our lead product candidate for the treatment of influenza, was incomplete. The Letter requested additional information related to our background technology to clarify information that we provided in our previous response to the clinical hold letter. We are working to respond on an expedited basis to provide the FDA with this information. If the FDA is satisfied with our follow-up response we believe we will be able to initiate our Phase I clinical trial on AVI-7100 in the first half of 2011.

Item 2.02 Results of Operations and Financial Condition.

We do not believe that the delay caused by the receipt of the Letter, or our response to it, will impact our previously announced financial guidance for 2011. Pursuant to the rules and regulations of the Securities and Exchange Commission, the foregoing disclosure under Item 2.02 is deemed to have been furnished to, but not filed with, the Securities and Exchange Commission.

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are identified by such words as believe, expect, anticipate and words of similar import and are based on current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. All statements other than historical or current facts, including, without limitation, statements about our ability to respond on an expedited basis to the Letter, our ability to satisfy the FDA, the timing of clinical trials and the impact of the clinical hold on our financial results and condition. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These statements, like all statements in this report, speak only as of their date.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVI BioPharma, Inc.

By: /s/ Christopher Garabedian
Christopher Garabedian
President and Chief Executive Officer

Date: March 14, 2011